Trimpex® (trimethoprim oral solution)

Policy # 00616
Original Effective Date: 05/16/2018
Current Effective Date: 06/08/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Trimpex®‡ (trimethoprim oral solution) for the treatment of acute otitis media or uncomplicated urinary tract infection to be **eligible for coverage**** when the patient selection criteria are met**.**

Patient Selection Criteria

Coverage eligibility for Trimpex (trimethoprim oral solution) will be considered when the following criteria are met:

- The patient has a diagnosis of acute otitis media; AND
    - Patient is older than 6 months of age and younger than 18 years of age; AND
    - Patient has tried and failed (e.g. intolerance or inadequate response) Primsol™‡ (trimethoprim oral solution) for at least 10 days unless there is clinical evidence or patient history that suggests that Primsol will be ineffective or cause an adverse reaction to the patient; OR

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- The patient has a diagnosis of uncomplicated urinary tract infection; AND
    - Patient is 18 years of age or older; AND
    - Patient has tried and failed (e.g. intolerance or inadequate response) Primsol (trimethoprim oral solution) for at least 10 days unless there is clinical evidence or patient history that suggests that Primsol will be ineffective or cause an adverse reaction to the patient; AND

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*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- Patient has tried and failed generic trimethoprim tablets (e.g. intolerance or inadequate response) for at least 10 days unless there is clinical evidence or patient history that suggests that generic trimethoprim tablets will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Trimpex (trimethoprim oral solution) for acute otitis media when the patient has NOT tried and failed Primsol (trimethoprim oral solution) for at least 10 days to be **not medically necessary.****

Based on review of available data, the Company considers the use of Trimpex (trimethoprim oral solution) for uncomplicated urinary tract infection when the patient has not tried and failed Primsol (trimethoprim oral solution) AND generic trimethoprim tablets for at least 10 days each to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Trimpex (trimethoprim oral solution) for indications other than acute otitis media in children older than 6 months and uncomplicated urinary tract infection in adults to be **investigational.***

Background/Overview

Trimpex is a 10 milligram per mL (mg/mL) bubble-gum flavored oral solution of the antibiotic trimethoprim. Trimethoprim is also available as a generic oral tablet and as Primsol, another 10 mg/mL bubble-gum flavored oral solution. Trimpex is indicated for the treatment of pediatric patients with acute otitis media due to susceptible strains of *Streptococcus pneumoniae* and

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Haemophilus influenzae and for adult patients with uncomplicated urinary tract infection due to susceptible strains of *Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae, Enterobacter* species, and coagulase negative *Staphylococcus* species. It is important to note that *Moraxella catarrhalis* isolates were found to be consistently resistant to trimethoprim *in vitro* and therefore an alternative antimicrobial should be used when an infection with *Moraxella catarrhalis* is suspected. Trimpex is also NOT indicated for prophylactic or prolonged administration in otitis media at any age. The recommended dose of Trimpex for pediatric patients with acute otitis media is 10 milligrams per kilogram (mg/kg) given in divided doses every 12 hours for 10 days. The usual oral adult dosage is 100 mg every 12 hours or 200 mg every 24 hours for 10 days.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Trimpex solution is indicated for pediatric patients with acute otitis media due to susceptible strains of *Streptococcus pneumoniae* and *Haemophilus influenzae* and for adult patients with uncomplicated urinary tract infection due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *Enterobacter* species, and coagulase negative *Staphylococcus* species.

Rationale/Source

The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests an alternative formulation of trimethoprim (e.g. Primsol oral solution or generic trimethoprim tablets) will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using Trimpex over Primsol or generic trimethoprim tablets.

References

1. Trimpex [package insert]. Key Therapeutics. Flowood, MS.

Policy History

Original Effective Date: 05/16/2018
Current Effective Date: 06/08/2020
05/03/2018 Medical Policy Committee review
05/16/2018 Medical Policy Implementation Committee approval. New policy.

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05/02/2019 Medical Policy Committee review
05/15/2019 Medical Policy Implementation Committee approval. No change to coverage.
05/07/2020 Medical Policy Committee review
05/13/2020 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 05/2021

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.